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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/023,335	12/17/2001	Eva Redei	053662-5002-01	4164

28977 7590 05/21/2003

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EXAMINER

LI, QIAN J

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 05/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/023,335

Applicant(s)

REDEI ET AL.

Examiner

Q. Janice Li

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 April 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-63 is/are pending in the application.
- 4a) Of the above claim(s) 1,2,5-55 and 57-63 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 3,4 and 56 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 December 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election of Group II, claims 3, 4, 56, in Paper No. 8 without traverse is acknowledged. Claims 1, 2, 5-55, and 57-63 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 8.

Claims 3, 4, and 56 are under current examination.

### ***Priority***

This application is a continuation-in-part of U.S. application 09/590,837, which claims the benefit of U.S. provisional application 60/105,459, filed 10/23/1998, and which has now been abandoned. Applicants should amend the specification to indicate the status of the parent application 09/590,837.

### ***Drawings***

The drawing for figure 5 is objected to under 37 CFR 1.83(a) because the pictures in figure 5 are so unclear that they fail to show the amygdala RNA from different rats as described in the specification. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). A proposed drawing correction or corrected drawings are required

in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 3 and 4 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter, i.e. the claimed WLI rat encompasses and is indistinguishable from a product of nature. This is because the specification defines WLI rat as the progeny of a mating between two commercially available WKY rats and exhibits a trait of immobility score of lower than about 8 in a forced swim test (Specification, page 39, table and legend). Since the mating could occur in nature, certain individuals in the progeny derived from the mating of two WKY rats would inherently have the recited trait.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3, 4, and 56 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to

which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered when determining whether the disclosure satisfies the enablement requirements and whether undue experimentation would be required to make and use the claimed invention are summarized in *In re Wands*, (858 F2d 731, 737, 8 USPQ 2d 1400, 1404, (Fed Cir.1988)). These factors include but are not limited to the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability of the art, the breadth of the claims, and amount of direction provided. The factors most relevant to this rejection are the nature of the claims relative to the state of the art and the levels of the skilled in the art.

Claims are drawn to a WLI rat and cells isolated from the rat. The specification teaches that WLI rats are made by breeding the male and female inbred WKY rats who exhibit a less depressive behavior, such as immobility score of lower than about 8 in a forced swim test (Specification, page 39, table and legend). The specification discloses mating a male WKY rat having a FST immobile score of 7 and a female WKY rat having a FST immobile score of 6, and obtained twelve F1 WLI rats having an average FST immobile score of about 3. However, the specification fails to teach the frequency of finding a WKY rat with the low FST immobile score in WKY rat population, and the specification fails to teach the predictability and persistency of getting the recited trait in progenies of F2 and above, thus, fails to provide sufficient guidance to enable the claimed invention. In view of the state of the art in animal breeding, *Harris et al* (J Anim Sci 1994,72:2178-2200) teach from fifty years of breeding experience that the different

Art Unit: 1632

traits in breeding animals may vary widely, some traits may only express once and others last for a life time, "THESE FACTORS MAKE WISE SELECTION A COMPLICATED AND UNCERTAIN PROCEDURE" (right column, page 2178). Such uncertainty could be seen in the teaching of the specification, where the FST immobile scores vary significantly among progenies derived from mating of parents having similar FST immobile scores. For example, when the parents having the FST immobile scores of 13 and 21 respectively (row 2 in the table of page 39), the progenies could have an average score that is large than 24, whereas other parents having similar FST immobile scores of 15 and 27, some of the F1 rats may have an average score of only 4.8 (male rats in row 4, the table of page 39). The specification only teaches one pair of WKY rats having low FST immobile score, which generated the F1 progeny of the claimed WLI rats. However, it is unclear and the specification fails to teach the frequency of finding a WKY rat with the low FST immobile score in WKY rat population, predictability and persistency of getting the recited trait in progenies of F2 and above, In view of such, it was highly unpredictable to reproducibly obtaining the WLI rats.

For reasons set forth above, it appears that the skilled artisan could not predictably and reproducibly obtain the WLI rats having the given phenotype required by the claims. Accordingly, in view of the quantity of experimentation necessary to obtain the WLI rats, and the lack of predictability of the art, one skill in the art could not practice the invention without undue experimentation.

Applicants are reminded that the claimed invention must be readily available or obtainable by a repeatable method set forth in the specification or other wise known and

readily available to the public. If it is not so obtainable or available, an enabling deposit of the embryo generated by the mating of 3H1 and F6 (parents of the claimed WLI rats) may satisfy the requirements of 35 U.S.C. 112, first paragraph.

If a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants, or a statement by an attorney of record over his or her signature and registration number, stating the instant invention will be irrevocably and without restriction released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein. If a deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809 and MPEP 2402-2411.05, Applicant may provide assurance of compliance by affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number showing that:

- (a) during the pendency of the application, access to the invention will be afforded to the Commissioner upon request;
- (b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
- (c) the deposit will be maintained in a public depository for a period of 30 years, or 5 years after the last request or for the enforceable life of the patent, whichever is longer;
- (d) a test of the viability of the biological material at the time of deposit ( see 37 CFR 1.807); and
- (e) the deposit will be replaced if it should ever become inviable.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3 and 4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are vague and indefinite because of the claim recitation, "about". The specification does not provide a standard for ascertaining the requisite range of the term "about", and thus the metes and bounds of the claims are unclear.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 3 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by *Paré et al* (Physiol & Behavior 1997;643-8) and as evidenced by Data Sheet of *Mouse Genome Informatics*.

Claims 3 and 4 are directed to a WLI rat characterized by a forced swim test immobility score of lower than about 8. The specification defines the WLI rat as a progeny of inbred WKY rats, who exhibit a less depressive behavior, preferably the



progeny is at least F1 generation, and preferably F2 generation colonies of less depressive WKY rats (Specification, page 38, example 1).

*Paré et al* teach that WKY rats are hyperresponsive to stress and prone to stress ulcer. However some *variability* have been reported. Although not relied upon, the data sheet of WKY rats by MGI teaches that inbred WKY rats have been established since 1971, thus, many generations of breeding have been performed. The progenies of the inbred WKY rats would intrinsically comprise those individuals whose parents exhibit less depressive behavior and who exhibit a forced swim test immobility score of lower than about 8. Thus, *Paré et al* anticipate the instant claims.

Claims 3, 4, and 56 are rejected under 35 U.S.C. 102(a) as being anticipated by *Begum et al* (Am J Physiol 1998 Jul;275:C42-9).

Claim 56 is drawn to cells isolated from the rats.

*Begum et al* teach WKY rats and obtaining isolated vascular smooth muscle cells from WKY rats (abstract). As indicated above, because the progenies of the inbred WKY rats would intrinsically comprise those individuals whose parents exhibit less depressive behavior and who exhibit a forced swim test immobility score of lower than about 8, thus, the rats used and cells isolated by *Begum et al* anticipate the instant claims.

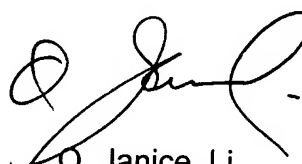
No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Q. Janice Li whose telephone number is 703-308-7942. The examiner can normally be reached on 8:30 am - 5 p.m., Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah J. Reynolds can be reached on 703-305-4051. The fax numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of formal matters can be directed to the patent analyst, Dianiece Jacobs, whose telephone number is (703) 305-3388.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235. The faxing of such papers must conform to the notice published in the Official Gazette 1096 OG 30 (November 15, 1989).



Q. Janice Li  
Examiner  
Art Unit 1632

QJL  
May 19, 2003